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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/088,876 | 01/16/2003 | Jason Peter Brown | A0000180/2-01-MG | 4968 |

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| EXAMINER | |
|---|---|
| CHANDRA, GYAN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/088,876 | BROWN ET AL. | |
| | Examiner | Art Unit | |
| | Gyan Chandra | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *6--53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/21/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group II, claims 1-20, 22-35, in the reply filed on 1/27/2006 is acknowledged. Because Groups 2-24 comprising polypeptide of SEQ ID NOs: 4-6, 10-12, 16-18, 23-24, 33-37, 41-44, and 53-55 are proteins, Applicant was under impression that they require same special technical feature. The attorney had left a message with the Examiner for seeking clarity on this. The Examiner telephoned the attorney Austin Zhang on 2/7/2006, to explain that Groups 2-24 comprise 23 different amino acid sequences and that each protein sequence requires special technical feature. In the restriction requirement, the amino acid sequences of SEQ ID NOs: 4-6, 10-12, 16-18, 23-24, 33-37, 41-44, and 53-55, in stead of listing one sequence for each group, separately, the amino acid sequences are placed in groups 2-24 together.

Attorney Zhang elected amino acid sequence of SEQ ID NO: 6 with traverse. The traversal is on the ground(s) that the amino acid sequences of SEQ ID NO: 4 and 5 share special technical feature with the protein of SEQ ID NO: 6. Because the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 4 is a few amino acids shorter that the amino acid sequence of SEQ ID NO: 6, these three polypeptide should be examined together. This argument is persuasive and therefore, Groups 2-4 (SEQ ID NO: 4, 5, and 6) are examined together. Applicant traverses the species election by stating that because all the listed screening assays use a soluble calcium channel $\alpha 2\delta$ subunit, and because all the listed ligands are amino acids, unity exists. Applicant's arguments are not persuasive because even though the screening methods are to utilize $\alpha 2\delta$ subunit

calcium channel but each channel comprises different amino acid sequence, therefore, each method is different screening assay. Further, the ligands listed in claims 49-52 are not disclosed to substitute for each other, functionally. The requirement is still deemed proper and is therefore made FINAL.

*Status of Application, Amendments, And/Or Claims*

Claims 1-53 are pending.

Claims 21, 23-34, 36-53 are withdrawn as being non elected invention.

Claims 1-20, 22 and 35 are examined to the extent they read on elected sequences of SEQ ID NO: 4, 5 or 6.

***Claim Objections***

Claims 6-20, 22, and 35 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 6-20, 22, and 35 have not been further treated on the merits.

Claim 3 objected for reciting non-elected inventions.

Applicant is advised to delete the non-elected invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Lerman et al ( US Patent No. 6, 441,156).

The claims are drawn to a calcium channel α2δ subunit that is (i) human α2δ subunit, SEQ ID NO: 4 or 5 or 6, (ii) soluble α2δ subunit, and (iii) the α2δ subunit retains functional characteristics of the full length or wild type α2δ subunit from which it is derived, naturally expressed in central cortex..

Lerman et al teach a calcium channel α2δ of SEQ ID NO: 4 which is 100% identical to the instantly claimed α2δ subunit of SEQ ID NO: 6 ( that comprises the amino acid sequence of SEQ ID NO: 4, and SEQ ID NO: 5), see attached sequence alignment- Appendix-A. They disclose that the mRNA which is about 5.3-5.5 kb in length that encodes α2δ polypeptide, and that the mRNA is highly expressed in lung and testis, and moderately expressed in brain, heart, spleen, and small intestine (column 12, lines 62-67 through column 13, lines 1-3). They teach that the α2δ protein is a 175 kDa protein which upon a post- translational cleavage makes a disulfide link between α2 and δ peptides (column 17, lines 30-32). They teach expressing the polypeptide in NCI-H1299 non-small cell lung cancer cells, and purifying the protein using polyacrylamide gel electrophoresis (see Example 8). Lerman discloses that the

drug gabapentin inhibits neuronal $Ca^{2+}$ currents and the $\alpha 2\delta$-1 has a very high affinity binding site for the drug gabapentin (col. 17, lines 61-65). Therefore, they teach performing a functional assay with soluble $\alpha 2\delta$ protein. Thus, Lerman et al. meet all the instantly claimed limitations.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B O'Hara

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Art Unit 1646
5 April 2006
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